PATENT
Docket No.52949-2000100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of: MARK SCHENA

Examiner: B. J. Foreman

Group Art Unit: 1634

Serial No.: 09/613,006

Filing Date: July 10, 2000

For: MICROARRAY METHOD OF GENOTYPING MULTIPLE SAMPLES AT MULTIPLE LOCI

DECLARATION UNDER 37 C.F.R. § 1.132

I, Neil Winegarden declare and affirm that:

1. I am currently Head of Operations of the Microarray Centre at the University Health Network in Toronto, Ontario.

2. I am not an inventor in the above-referenced application.

3. I have read the above referenced application, and I understand the microarray method described in this specification.

4. As one of skill in the art, I understand the hybridization conditions described in this application to result in hybrids formed between polynucleotides of the array and complementary oligonucleotides.

5. I understand that the microarray method described in the specification would achieve simultaneous genotyping of multiple mammalian samples after a single round of hybridization.

6. Support for statements in paragraphs 4 and 5 is found as follows:

A) A means to generate polynucleotides from multiple samples using PCR for placement of resulting polynucleotides on arrays is disclosed in the specification on page 2, line 28 – page 3, line 1, and page 4, line 22 – page 5, line 17.

B) A means to generate microarrays of sample polynucleotides is disclosed on page 6, line 3 – page 7, line 29.

C) Conditions for hybridizing synthetic oligonucleotides to microarrays of polynucleotides are disclosed on page 7, line 30 – page 8, line 14.

D) Methods of labeling oligonucleotides and detecting hybridization of labeled oligonucleotides to polynucleotides on microarrays is disclosed on page 8, line 15 – page 10, line 11.

E) Detection of signal after a single round of hybridization is disclosed on page 13, line 17 – page 14, line 8. The specification states:

> Hybridization reactions were performed using 10 µl of Mixture 1 or Mixture 2 per microarray. The 10 µl mixture was applied to the microarray under a cover slip measuring 18 mm x 18 mm x 0.2 mm. Hybridizations were performed for 5.5 hours at 42°C in a hybridization cassette according to the instructions of the manufacturer TeleChem (Sunnyvale, CA). Following the 5.5 hour hybridization, the microarrays were washed to remove unhybridized material as follows: twice for 5 minutes in 2X SSC (0.3 M sodium chloride, 0.03M sodium citrate) and 0.2% SDS (sodium dodecyl sulfate) at 25°C, and once for 1 minute in 2X SSC (0.3 M sodium chloride, 0.03M sodium citrate) at 25°C.
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> Following the hybridization and wash steps, the microarrays were detected for genotyping information. For the direct labeling experiments involving Mixture 1, the detection step was performed by scanning the microarray for fluorescence emission immediately following the wash step.

Based on the above quotation from the specification, it would be the understanding of one of skill in the art that only one round of hybridization was performed, and thus only one round of hybridization and not more, is required to practice this invention.

7. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

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Executed this 13th day of December, 2002

Neil Winegarden